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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,607	09/12/2003	David H. Mack	003848.00131	7415

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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 02/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/660,607	<b>Applicant(s)</b> MACK, DAVID H.	
	<b>Examiner</b> Jeanine A. Goldberg	<b>Art Unit</b> 1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-129 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 18-129 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

1. This action is in response to the papers filed November 22, 2005. Currently, claims 18-129 are pending.
2. Upon initial search and consideration of the elected invention, a further restriction requirement was deemed necessary.

### **Restriction**

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 18-28, drawn to method for determining gene function, classified in class 435, subclass 6.
  - II. Claims 39-40 & 99-106, drawn to an array of nucleic acid probes, classified in class 536, subclass 24.3.
  - III. Claims 44 & 45, drawn to a method for analyzing gene expression using a computer, classified in class 364 , subclass 920.
  - IV. Claims 46-94, drawn to a method of diagnosis using hybridization, classified in class 435, subclass 6.
  - V. Claims 95-98, drawn to a method of identifying drugs, classified in class 435, subclass 70.1.
  - VI. Claims 109-115, drawn to a method of identifying drugs, classified in class 435, subclass 70.1.
  - VII. Claims 116-129, drawn to method of determining cell state, classified in class 435, subclass 6.

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4. Inventions II and I & III-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as a template for amplifying nucleic acids or for making labeled probes.

5. Inventions I, III-VII are independent and distinct inventions. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because they are methods having different method steps, different functions, different effects, and because they have different results such as mapping a gene network (invention I), detecting and comparing gene expression (invention II), determining gene function (invention III), analyzing gene expression (invention IV), diagnosing gene expression pattern (invention VI), identifying a compound as an anti-cancer drug (invention VII), analyzing gene expression under drug pressure (invention VIII), determining the state or stage of cells or tissue (invention IX), and using an in-cell assay to analyze specific gene function (invention X).

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4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

**Restriction Requirement Applicable to All Groups:**

6. The claims are drawn to a combination of genes, namely one or more genes. A restriction is applied to each Group. Specifically, Claim 46 is drawn to a set of nucleic acid molecules whose expression is induced or repressed by a regulatory molecule. Claim 49 provides at least 4 genes; Claim 50 provides at least 10 genes; Claim 51 provides at least 20 genes; Claim 52 provides at least 30...and Claim 59 provides 1000 genes, for example. Further Claim 60 is drawn to genes in Table 3. Claim 65, 66 provide specific genes in the alternative.

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As provided in MPEP 803.04, "Applicants will be required to select one combination for examination." The selected combination will be searched and examined. A combination may be as few as a single gene, as permitted by Claim 46 or as many genes as the combination of all the recited genes. Applicant is required to specifically indicate the single combination desired.

A search of genes A and B, for example is patentably distinct from a search for genes C and D.

All combinations containing the allowable sequences and any patentably indistinct sequences will be rejoined and allowed. Rejoinder will be permitted for claims requiring any allowable sequence(s). Any claims which have been restricted and nonselected and which are limited to the allowable sequence(s) will be rejoined and examined.

Should applicant traverse on the ground that the different combinations of nucleic acids are not patentably distinct, applicant should submit evident or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CAR 1.143).

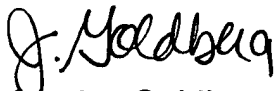
### **Conclusion**

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272- 0745.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

  
**Jeanine Goldberg**  
**Primary Examiner**  
January 17, 2006